

REMARKS

I. Support for the Amendments to the Claims

Claims 3, 11, 13, 21, and 23 have been amended.

Support for the amendments to claims 3, 11, 13, 21, and 23 can be found throughout the specification and claims as originally filed. The amendments to claims 3, 11, 13, and 23 eliminate the use of the words “substantially” or “about,” and support for these amended claims can be found in the original language of claims 3, 11, 13, and 23, respectively. Support for the amendments to claim 21 can be found in the language of original claims 1 and 21 and in the specification, e.g., on page 16, lines 10-12; from page 17, line 1, to page 18, line 3; on page 24, lines 13-17; and in the Examples.

II. The Form PTO-892 and the Information Disclosure Statements

The Office Action Summary lists a Notice of References Cited (PTO-892), but this was not enclosed and is not available in PAIR. Applicants wish to confirm whether a PTO-892 was to have been attached.

Applicants thank the Examiner for acknowledging the Information Disclosure Statements of March 31, 2005, and August 8, 2006.

III. The Rejection of Claims 3, 11, 21, and 23-24 under 35 U.S.C. §112, Second Paragraph, is Traversed in Part but Accommodated

The Examiner has rejected claims 3, 11, 21, and 23-24 under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Applicants respectfully traverse this rejection in part, but have accommodated the Examiner's request for amendment in the interests of timely prosecution.

Specifically, Applicants wish to draw the Examiner's attention to §2173.05(b)(D) of the Manual of Patent Examining Procedure ("MPEP") with respect to the use of the word "substantially" in claims 3, 11, and 23-24. Applicants traverse this rejection, but have eliminated this term from claims 3, 11, and 23-24 in order to accelerate prosecution.

Applicants have amended claim 21 to address the Examiner's rejection for lack of antecedent basis with respect to the phrase "the nucleus."

The Patent Office alleges that the phrase "substantially by non-ionic interaction" in claims 23-24 is vague and indefinite. It is unclear whether the Patent Office this rejection refers to the term "substantially" or whether it refers to "non-ionic interactions." As noted *supra*, Applicants have deleted the term "substantially." Applicants note that "non-ionic interactions" were well-known in the art at the time the invention was made and that it is described in the instant specification (see, e.g., page 13, lines 23-26). The term "non-ionic interactions" is a standard term in the art and includes van der Waals interactions, dipole-dipole interactions, dipole-induced dipole interactions, London dispersion forces, hydrogen bonding, and the like. Examples of non-ionic interactions are provided in the instant specification (see, e.g., page 13, lines 23-26) and in the language of claim 24.

Applicants respectfully submit that claims 3, 11, 21, and 23-24 fulfill the requirements of 35 U.S.C. §112, second paragraph, thereby placing these claims in condition for allowance, and request the Examiner's reconsideration accordingly.

IV. The Rejection of Claims 1-35 and 66 under 35 U.S.C. §103(a) over Mitchell in view of Burgoyne is Traversed

The Examiner has rejected claims 1-35 and 66 under 35 U.S.C. 103(a) as unpatentable over Mitchell (WO 00/21973; issued April 20, 2000) in view of Burgoyne (U.S. Patent 5,496,562; issued March 5, 1996). Applicants traverse the rejection and respectfully request reconsideration of these claims.

The Patent Office alleges:

Mitchell et al. disclose the method steps (a)-(e) as recited in instant claim 1 (See pg. 2, third paragraph) and the method steps as recited in claim 4 (See pg. 2, third paragraph). The nucleic acid is retained by the filter substantially in the absence of ionic interaction (See column 2, last paragraph), and by physically retarding the movement of the nucleic acid down the filter (See pg. 3, first paragraph). The nucleic acid is heated to an elevated temperature, whilst retained by the filter prior to elution and the temperature is about 90°C (See pg. 3, second paragraph, pg. 6, first paragraph, pg. 12, first paragraph and pg. 25, experiment 6). There is a solution for rupturing intact whole cells to leave condensed nuclear material and a lysis solution for lysing nuclear material (See pg. 3, third paragraph). The sample comprises whole blood, which has been treated with a red blood cell lysis solution, whilst the white cells containing the nucleic acid are retained by the filter as a retentate (See pg. 6, third paragraph). A filter material is selected which provides no barrier to cells, but enables the cells to be retained by the filter as a retentate (See pg. 6, second paragraph). The pore size of the filter is 4.5µm (See pg. 11, table 1). The filter used in the method comprises a plurality of fibers and has a substantially disordered structure, the fiber diameters are selected from the range of 1µm to 10µm (See pg. 9, fourth paragraph). The fiber is glass fiber, silica based or plastic based fiber (See pg. 10, first paragraph). It is possible to isolate nucleic acid in the absence of a chaotrope (See pg. 10, second paragraph). Genomic DNA is a desired target or nucleic acid is RNA (See pg. 15, fourth paragraph).

Mitchell et al. do not disclose the method steps (f)-(g) as recited in instant claim 1.

Burgoyne discloses that the blood-stained paper was dried, and sent through the ordinary mail so that it spent at least three days in the mail, and had the DNA extracted from it (See column 4, lines 41-45). A card loaded with a DNA sample is air dried at room temperature (See column 5, lines 43-44). [Par. 4; pp. 3-4.]

Applicants respectfully disagree. Essentially, the Patent Office alleges that Mitchell discloses steps (a)-(e), but not (f)-(g) (i.e., drying and storing the nucleic acid on the solid phase medium). The Patent Office alleges that Burgoyne discloses drying DNA samples on a card and storing them. Claims 1-34 depend, either directly or indirectly, on claim 1.

In the present invention, the improvement is more than the predictable use of prior art elements according to their established functions.

Mitchell uses glass or plastic for the solid phase medium (p. 10). The cells are lysed in the matrix (e.g., p. 8, pp. 14-15, etc.), and the isolated DNA is eluted (e.g., p. 11). Example 1 (see p. 18) describes a method whereby whole blood is added to the column and filtered to waste. A red blood cell lysis buffer is added (to lyse RBC's) and filtered to waste. SDS is added and filtered to waste, TE is added and filtered to waste (twice). The column is heated, additional TE is added, and the DNA in solution is captured by elution. The SDS and TE are not part of the same solution, but the current claim 1 is directed to "a solution comprising a surfactant or detergent." In Mitchell, they are added separately and filtered to waste. Finally, as the Patent Office concedes, there is no drying of the DNA on the filters and no storage.

The Patent Office alleges, however, that Burgoyne describes the drying and storage. Burgoyne uses cellulose or plastic for the solid phase medium (c. 2). The DNA can be stored, or it can be extracted or eluted (cc. 4-6). Burgoyne describes a solution of SDS, EDTA, and Tris. Burgoyne also describes a composition comprising a weak base, a chelating agent, an anionic surfactant or anionic detergent and optionally uric acid or a urate salt. Unlike the present invention, however, the card comprises the composition prior to its contact with the sample. In the present invention and in Mitchell, the solutions are added after the sample.

In Mitchell, the lysis solutions are added sequentially in order to function. Burgoyne uses a chemical composition of the base, chelator, detergent and uric/urate salt that is already deposited on the solid matrix.

In the present language of claim 1, the sample is added to the solid phase medium first and then the archiving agent (a solution comprising a surfactant or detergent; step d), followed by drying and storage. In claims 19, 35, and 66, the solution simultaneously comprises a surfactant or detergent, a weak base, and a chelating agent. In claim 20, the solution simultaneously comprises a surfactant or detergent, a weak base, a chelating agent, and uric acid or a urate salt. The present invention is distinguishable in that one solution is added to the sample and not sequentially as in Mitchell.

Another distinction is the drying of the sample for storage and archiving of DNA. In Mitchell states (p. 7, ll. 15-20) that if the filter is allowed to dry the DNA is recoverable but sheared and, where the method is carried out in a column, indicates the need for using a vapor block to prevent drying from occurring, because this is undesirable. Such a method is, therefore, ill-suited to archiving.

Meanwhile, while Burgoyne discloses drying the matrix, it fails to mention adding a solution to the already applied sample. Instead, the solution of Burgoyne is added to the matrix and dried prior to application of the sample.

Nothing in Mitchell would suggest to one of skill in the art that it should be combined with Burgoyne, or vice versa, to produce the present invention (single solution application and subsequent drying for archiving). In particular, one of skill in the art would not cite Mitchell's method for archiving since the method disclosed therein is for rapid preparation of DNA immediately after the addition of the sample.

Thus, there is no teaching, suggestion or motivation in Mitchell or Burgoyne that would have led on of ordinary skill in the art to combine and/or modify these teachings to arrive at the claimed invention, nor is the present invention merely a variation on known work in the field of endeavor that one of ordinary skill in the art would have been predictable to one

of ordinary skill in the art, nor is it chosen from a finite number of identified, predictable solutions, with a reasonable expectation of success. In the present invention, therefore, the improvement is more than the predictable use of prior art elements according to their established functions.

Finally, with respect to claim 13, the Patent Office alleges that, because the claim is directed to a pore size of "about 0.2 μm to about 2.7 μm ," it can be interpreted to cover a pore size of 4.5 μm as disclosed by Mitchell. Applicants respectfully traverse this rejection, but have amended claim 13 to eliminate the term "about" in order to accelerate prosecution.

Applicants respectfully submit that claims 1-35 and 66 fulfill the requirements of 35 U.S.C. §103(a), thereby placing these claims in condition for allowance, and request the Examiner's reconsideration accordingly.

CONCLUSION

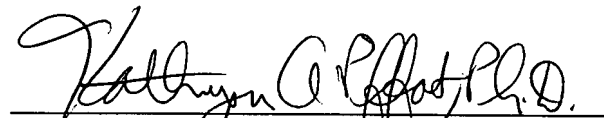
It is believed that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

Applicants hereby request a two-month extension of time for the Amendment and accompanying materials. If, however, a petition for an additional extension of time is required, then the Examiner is requested to treat this as a conditional petition for an additional extension of time and the Commissioner is hereby authorized to charge our deposit account no. 04-1105 for the appropriate fee. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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